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Published in:
Journal of Viral Hepatitis

DOI:
10.1111/jvh.13016

Publication date:
2019

Document Version
Author accepted manuscript

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Article type : Original Paper

Full Title

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Running title

HCV testing following Penrose Inquiry

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jvh.13016

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Acknowledgements

This work was undertaken under the terms of reference of the Scottish Government's Penrose Short Life Working Group. The authors would like to thank the members of this group for their guidance and input. The authors would also like to thank colleagues from the Hepatitis C testing laboratories that contribute data to the Hepatitis C test database.

Abstract

The final report of the Penrose Inquiry into historic transmission of HIV and hepatitis C (HCV) through blood transfusion/products in Scotland was published in March 2015 and recommended "everyone who had received a blood transfusion prior to 1991 and who had not had a test for HCV should be offered one". A targeted awareness-raising campaign to encourage such individuals to be tested was launched in October 2016. We examined HCV testing undertaken in 2015-16 in three NHS boards in Scotland to evaluate impact of these events. Statistical process control was used to monitor trends in individuals tested and those mentioning transfusion. HCV positivity was calculated and multivariate logistic regression was used to examine factors associated with mention of transfusion. 22,842 individuals received an HCV test in 2015-16 and 3% of those with clinical information mentioned transfusion. For all HCV tests, the week following the Penrose Report was significantly higher and for tests indicating transfusion, the 3 weeks following were significantly higher. There was no significant increase following the awareness-raising campaign. Women and those aged over 50 years were the most likely to have mentioned transfusion. Overall HCV positivity was 3.7% and <1% for the transfusion group. The impact of both intense media coverage and the government funded awareness-raising campaigns in terms of HCV test

uptake was modest and short-lived. Our findings highlight the challenges of case-finding for HCV and the limited impact of awareness-raising. This can be used by other countries aiming to identify those infected through historic blood transfusion.

Introduction

The final report of the Penrose Inquiry into the historic transmission of HIV and hepatitis C (HCV) through blood and blood products in Scotland was published on 25th March 2015.[1] The report had one recommendation: everyone who received a blood transfusion prior to 1991 and had never been tested for HCV should be offered one. The Prime Minister of the United Kingdom and First Minister of Scotland apologised to the victims and their families, while some patient groups branded the report a "whitewash" and publicly burned copies.[2,3,4] There was considerable media coverage of the report's publication and subsequent response. Much of this coverage included the recommendation that historic blood transfusion recipients should be tested for HCV.[5,6,7]

The Scottish Government established a Short Life Working Group (SLWG) to consider what specific actions could be taken in the context of the Inquiry recommendation. This group estimated that 100,000 people who had received a blood transfusion prior to 1991 in Scotland were alive and eligible for testing under the recommendation and that only 100 of these (0.1%) were estimated to be HCV infected and 30 remained undiagnosed. The SLWG considered various approaches to identify those eligible for testing: retrospective testing of blood donor specimens, interrogation of clinical records for transfusion history, notifying all GP patients about pre-1991 transfusion risk, delivery of a targeted awareness raising campaign, and general population screening. The SLWG recognised the need to ensure that the response was cost-effective and proportionate to the scale of the problem and most of

these options were deemed inappropriate based on their prohibitively high costs and likely low effectiveness. A targeted awareness campaign to encourage past blood transfusion recipients to come forward for testing was therefore recommended, with the understanding that the effectiveness of identifying the small number of HCV infected, undiagnosed individuals was uncertain and should be evaluated.[5]

The main element of this campaign was information leaflets and posters (Appendix 1). A total of 380,000 fliers and 7,500 posters were distributed with three quarters sent to 966 general practices in Scotland and the remainder sent to a variety of settings including pharmacies (7%), dentists (5%), and care homes (5%). These materials sign-posted those who may have had a transfusion prior to 1991 to the NHS Inform website (www.nhsinform.scot), a support helpline and to their general practitioner (GP).[8]

The identification of those infected with HCV through blood transfusions prior to 1991 has been attempted in various countries worldwide. The most common approach to this has been to undertake look-back studies using records of those known to have received a blood transfusion where the HCV status of the donor was either known to be positive or unknown.[9-14] Blood transfusion risk has also been included in general awareness-raising campaigns for HCV, including those undertaken in Scotland in recent years, alongside the other risk groups.[15-18] Campaigns aimed exclusively at blood transfusion recipients have been rare. [19]

Here we present results of analysis of HCV test uptake following the intense media coverage of the Penrose Report publication in 2015 and the government funded awareness-raising campaign targeting this risk group in 2016 to examine the impact of these two different interventions on HCV test uptake and those coming forward for testing.

Methods

Data source

Data from the Scottish Hepatitis C Test database were analysed. The methods for this surveillance system have been described previously. As a sentinel surveillance system, the Hepatitis C Test database includes data from the four largest NHS board areas (out of fourteen across Scotland) and covers 75% of testing undertaken in Scotland. Key fields in this database include: limited patient identifiers (first initial, soundex code of surname, sex, date of birth; Community Health Index (CHI) number); requesting clinician information (address and health board); test information (specimen date and anti-HCV result); and a free-text clinical information field.[20]

Preparation of data

Data on HCV testing undertaken in the labs that service three NHS board areas NHS Lothian, Grampian and Tayside (serving 35% of the Scottish population) were included in this analysis. One HCV Test database participating lab in NHS Greater Glasgow and Clyde was excluded as no clinical details were available for interrogation. HCV test data for 2015 and 2016 were broken down into weeks (excluding week 1 in 2015 and 52 in 2016 as these weeks included 2014 and 2017 data respectively) and duplicate tests were removed. The Penrose Inquiry Final Report was published in week 13 of 2015 and the SG awareness campaign launched in week 41 of 2016, data for the periods 11 weeks prior to publication date and 10 weeks post awareness campaign launch were reviewed.

Analysis was restricted to testing undertaken in general practice as patients were considered most likely to request a test in this setting. GPs received a Chief Medical Officer (CMO) letter about screening of historic blood transfusion recipients in week 13 of 2015 and week 38 in 2016. Individuals born after 1991, when HCV screening of transfused blood began, were excluded.

The reason for testing was sourced from the clinical information field, which includes information provided at the time of the HCV test. Any test with clinical details available and/or mention of blood transfusion and/or Penrose was flagged. Each test record was categorised as (1) "clinical information available, no mention of transfusion", (2) "clinical information available and mention of transfusion" or (3) "no clinical information"

Statistical analysis

Trends in HCV testing across 2015/2016 were analysed using statistical process control (SPC) to monitor changes in trends and large aberrations. SPC is commonly used in a variety of settings, including health, for quality improvement purposes by distinguishing between "common cause" or normal variations and "special cause" or unusual variations in trend data.[21] SPC has also been used to analyse routinely collected data for research. [22] The SPC output includes the mean number of tests carried out per week and upper and lower control limits. The control limits are set at three standard deviations above and below the mean and so represent 99% confidence intervals. Normal variation occurs between these limits and any values that fall outside of these limits are significant outliers at the 1% level, this allows for a greater degree of "noise" in the variation and confidence that any values outside of the limits are true outliers.

Factors, including sex, age at time of test and the Scottish Index of Multiple Deprivation (SIMD), associated with mention of transfusion at the time of HCV testing were examined using logistic regression. Multivariate analyses were undertaken and interaction between factors was also considered.

HCV antibody (anti-HCV) positivity is provided for all groups.

Results

During the study period, 22,842 individuals (11,769 in 2015 and 11,073 in 2016) received an HCV test. Table 1 shows characteristics of those tested. The majority were aged <50 years (60% in 2015 and 57% in 2016); the majority were in the least deprived, SIMD quintiles 3-5, areas (62% in 2015 and 61% in 2016) and the gender split was almost equal.

Following interrogation of the clinical details, 78% (n=17,816) contained clinical information but did not mention transfusion, 3% (n=580) contained clinical information including transfusion (e.g. "blood transfusion as baby, worried RE: Penrose Inquiry"; "Transfusion in 1984"), and 19% (n=4,446) did not contain any clinical information. Twenty-two tests mentioned "Penrose" in 2015 and no tests mentioned this risk in 2016.

Testing Trends (Figure 1)

Figure 1 shows trends in HCV testing during the study period for: all tests (figure 1a), those with clinical information but no mention of transfusion (figure 1b), and those with clinical information including transfusion (figure 1c). For all HCV tests, one significant outlier, where the number of all HCV tests exceeded the normal range, was identified in week 14 of

2015, which relates to the week after publication of the Penrose report (390 tests). One significant outlier, where the number of HCV tests was below the normal range, was identified in the clinical information and no mention of transfusion group in week 53 (96 tests) although this was an incomplete week of data. For HCV tests where transfusion was mentioned, three significant outlier weeks, where the number of HCV tests exceeded the normal range, were identified: in week 14 (106 tests), week 15 (76 tests) and week 16 (49 tests). No significant outliers were observed in relation to testing activity in the weeks immediately following the 2016 awareness campaign.

Excluding the weeks following the report publication and the awareness-raising campaigns, where the number of tests had increased, an average of 2 HCV tests mentioning transfusion were expected per week (figure 1c). In the seven weeks following the publication of the Penrose report, the median number of tests mentioning transfusion was 25 which represented a 13 fold-increase on the expected number. In the 10 weeks following the launch of the awareness-raising campaign, the median number of tests mentioning transfusion was 10, which represents a 5 fold increase.

Determinants of Blood Transfusion related testing

Table 2 shows characteristics of all individuals tested for HCV with clinical details and those with mention of transfusion. Those in the transfusion group were disproportionately female (82.8% compare with 49.0% of all clinical details), over 50 years old (80.5% compared with 42.2%) and less deprived (56.7% residing in the least deprived two quintiles compared with 43.2%).

In the regression analysis, females were 3.9 times more likely to mention transfusion than males (P<0.001) and those over 50 years of age were 4.9 times more likely than those under the age of 50 (p<0.001). Compared with the most deprived SIMD quintile (SIMD 1), those living in quintiles 3, 4 and 5 were significantly more likely to have transfusion mentioned (AOR of 2.2, 2.7 and 2.6, respectively).

Interactions between factors were considered but none were found to be significant.

HCV Positivity

HCV positivity was 3.7% for all tests, 3.5% for those with clinical information but no mention of transfusion, and <1% for the transfusion group. During the study period, there was not significant variation in HCV positivity among the three groups (all positives, all positives with no mention of transfusion or positives with mention of transfusion).

Discussion

This study examined the impact on HCV testing of (1) a non-targeted media event following publication of the Penrose Inquiry Final Report, which included the recommendation that anyone who had received a blood transfusion prior to 1991 should be offered a test for HCV, and (2) a targeted awareness-raising campaign to address this recommendation. [1,8]

Several days of intense media coverage were followed by a statistically significant increase in HCV testing in primary care. When comparing HCV tests in 2015 and 2016, the observed significant increase in testing was related to tests with mention of blood transfusion/ Penrose only. Testing returned to previous levels seven weeks after the media attention subsided.

Following the launch of the awareness-raising campaign, no statistically significant increase in HCV testing was observed. However, there was a modest rise in the number of tests that mentioned blood transfusion. Beyond statistical significance, however, the number of additional tests that may be attributed to the media coverage or awareness-raising was low, only 580 tests mentioning blood transfusion or Penrose in 2015-16 and 448 in the weeks following the interventions, when compared with the estimated 35,000 people eligible (35% of the 100,000 estimated number of those who received a blood transfusion prior to 1991 in Scotland and assuming that they were equally distributed throughout the country) for testing under the Penrose Inquiry recommendation. [5] While it is probable that some proportion of the tests without clinical details or with no mention of transfusion were among transfusion recipients it is unlikely to make a significant impact on the gap between the numbers reported here and the eligible population. Further analysis found that women aged 50 years and older were the most likely to have mentioned blood transfusion at the time of their test. HCV positivity was found to be low, which was consistent with the estimated number of blood transfusion recipients thought to be positive.

Media coverage has been widely demonstrated to increase awareness of, and screening for, various conditions.[23] This has the greatest impact when coverage surrounds a celebrity patient.[,24,25,26,27] A study of HIV testing in Scotland found that television campaigns (average increase of 46% in HIV tests over 2 months) had a greater impact on testing than the non-television campaigns (average increase of 6%)[28]. The short-lived increases in HIV testing observed in that study are consistent with the data presented here that show increases in HCV testing that last only seven weeks after publicity subsided. A systematic review examining the impact of mass-media campaigns on health behaviour found that the highest likelihood of success was among one-off target behaviours, such as screening, rather than habitual or ongoing, such as changes to diet or physical activity. However, the impact of

such campaigns was likely to be short-lived, which is consistent with our findings.[29] Another review of targeted HCV testing interventions found that media/information-based interventions were somewhat effective in increasing test uptake compared with no targeted testing (RR=1.26, 95% CI 0.97 to 1.64).[30] However, these were less effective than practitioner-based interventions, where in-practice support was provided compared with no targeted testing (RR=2.24, 95% CI 1.44 to 3.48). The most effective interventions were targeted at people who inject drugs (PWID). Risk-based screening among non-PWID risk groups poses a particular challenge. Inability to recall past risk factors and the perception that they were not at risk of HCV are well established barriers to treatment related to the patient, particularly in an older cohort.[31,32]

Following evidence that HCV had been transmitted through anti-D immunoglobulin in Ireland in 1994, a general screening programme for recipients of blood transfusions prior to 1991 was launched. This included considerable media coverage and communication with GPs and lead to almost 15,000 people, mainly women, being tested by between 1995 and 2002, with one third of these presenting in the first four months of the programme. While the combination of media coverage followed by an HCV screening programme is closest to the Scottish experience described here, a key difference in the Irish approach was the relatively short length of time (4 years) between the most recent HCV exposures and the screening programme, which contrasts with the interventions studied here which took place 25 years after the last exposures in 1991 [19]

In 2017, a UK-wide inquiry into infected blood and blood products was announced by Prime Minister Theresa May. [33] The terms of reference of the Infected Blood Public Inquiry, chaired by Sir Brian Langstaff, cover a wide range of areas and include an aim "to ascertain the numbers of people infected (directly or indirectly) in consequence of the use of infected blood" and to examine "the nature and extent of any attempt to identify those who may have

been infected and might benefit from treatment...". [34] Based on the Scottish experience, it is likely that there remain a proportion of transfusion recipients throughout the rest of the UK who have not yet been tested for HCV and there may be a similar consideration as to how to find them. Our findings demonstrate that a media campaign and targeted awareness-raising aimed at historic transfusion recipients has had limited impact in increasing testing. Similarly, awareness-raising initiatives aimed at increasing HCV screening and case-finding among GPs has been found to have limited impact in changing testing practices in primary care. [33] Surveys of GPs in Scotland undertaken in 2007 and 2013 (before and after a variety of government-led awareness raising initiatives) found that the offer of HCV tests was poor for recipients of a blood transfusion prior to 1992, with 55% of respondents in 2007 and 46% in 2013 reporting "never/rarely" offering a test to this group. This compared with 2% of GPs in both surveys reporting "never/rarely" offering current IDU an HCV test.

In Scotland, it is estimated that approximately 15,500 individuals with chronic HCV infection remain undiagnosed, of whom around 30 have acquired their infection through blood transfusion. [34] Given the limited impact of the media coverage and awareness-raising campaign, identification of historic blood transfusion recipients for screening should be incorporated into a broader case-finding screening strategy within primary care. There are several alternatives to awareness-raising, which could be utilised. Practitioner-based interventions have been shown to be effective in identifying former PWID in primary care. [29,35,36] This could be expanded to identify individuals who may have had a blood transfusion in the past. A growing body of evidence has demonstrated that electronic clinical reminders in patient management system can increase HCV test uptake and case-finding and again, this could be used to flag individuals who may have had a blood transfusion. [37,38] While less established, opt-out testing in primary care has also been demonstrated to increase HCV testing in primary care. [39]

Using volunteered, free-text information to categorise risk will undoubtedly miss some blood transfusion recipients who were tested but no mention of this was made on the request. Similarly, some individuals who reported a blood transfusion risk may not have received one before 1991. The Short Life Working Group acknowledged that it is unclear how many of the uninfected blood transfusion recipients had already come forward for testing and would therefore not do so following these interventions, which would reduce the upper estimate for eligible individuals as the Inquiry recommendation states that those who had received blood prior to 1991 and "had never been tested for HCV" should be offered one. As we used secondary surveillance data only, it has not been possible to determine whether the increase occurred as a result of the patients coming forward for testing, their clinicians being more aware of the need to offer an HCV test or a combination of both. Similarly, this analysis does not take account of offers of a test that a GP might make but the patient then refuses. We examined data from three NHS areas, which represent one third of the Scottish population and so the results may not be entirely representative of the whole country. Only ten weeks of follow up were available for the awareness-raising campaign and there may have subsequently been more individuals tested as a result of this campaign. Despite these limitations, our data demonstrate obvious trends in HCV test uptake following these interventions and utilising the same method allows for a comparison of the two.

We examined uptake of HCV testing following two key events, the media coverage of the Penrose Inquiry report and an awareness-raising campaign targeting these individuals. Media coverage led to a statistically significant but short-lived increase in testing in this group, while the awareness-raising campaign resulted in more limited increases. Given the large number (100,000) of those eligible to be offered an HCV test under the recommendation of the Penrose Inquiry, the impact of both the intense media coverage and the government funded awareness-raising campaigns in terms of HCV test uptake was modest. Our findings

highlight the challenges of case-finding for HCV, particularly in less common risk groups, and the limited impact of awareness-raising. Instead, measures such as educational initiatives targeted at professional groups, electronic reminders, opt-out testing, or practitioner-based support in primary care should be considered. These findings can be used by other resource rich countries aiming to identify those infected through historic blood transfusion.

Acknowledgements

This work was undertaken under the terms of reference of the Penrose Short Life Working Group. The authors would like to thank the members of this group for their guidance and input. The authors would also like to thank colleagues from the Hepatitis C testing laboratories that contribute data to the Hepatitis C test database.

What is already known on this subject?

The Penrose Inquiry final report, published in March 2015, had the single recommendation that "that the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV". It is estimated that 100,000 people are eligible to be tested.

What this study adds?

Several days of intense media coverage of the Penrose Inquiry final report publication and a government-led awareness-raising campaign led to modest and short-term increases in HCV testing in primary care.

Media coverage and information-based awareness-raising is insufficient to reach the estimated 100,000 individuals eligible for testing under the Penrose Inquiry recommendation. Identification of historic blood transfusion recipients for screening should be incorporated into a broader case-finding screening strategy within primary care

Contributors

AM and AW contributed equally to this paper. AM, AW, and SH designed the analysis. AM and AW analysed the data and wrote the first draft. DG was Chair of the Penrose Short Life Working Group. All authors contributed to subsequent drafts of the manuscript and have approved the final version.

Competing interests: None

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Table 1: Comparison of characteristics of individuals tested for HCV test in primary care in 3 large NHS boards in Scotland by year and following interventions.

Characteristic		Total number of people tested					Total number of people tested with mention of "transfusion" in clinical details				
		2015		2016			Post Penrose publication (wks 13-20)		Post SG awareness campaign (wks 42-51)		
		N	%	N	%	*p-value*	N	%	N	%	*p-value*
All		11769		11073			325	100.0	123	100.0	
Sex	Male	5933	50.4	5673	51.2		51	15.7	21	17.1	
	Female	5836	49.6	5400	48.8	0.215	274	84.3	102	82.9	0.723
Age Group (years)	<50	7011	59.6	6343	57.3		59	18.2	20	16.3	
	50+	4758	40.4	4730	42.7	<0.001	266	81.8	103	83.7	0.639
SIMD quintile	1/2 (most deprived)	4371	37.1	4256	38.4	0.043	66	20.3	31	25.2	0.262
	3/4/5 (least deprived)	7303	62.1	6744	60.9	0.075	248	76.3	92	74.8	0.739
	Not Known	95	0.8	73	0.7	0.191	11	3.4	0	0.0	0.039

Table 2: Factors associated with the mention of blood transfusion and/or Penrose in the clinical details of an HCV test in primary care in 3 large NHS boards in Scotland, 2015-16.

Characteristic		Total number of people tested for HCV during study period with clinical details N (%)	Mention of blood transfusion and/or Penrose in clinical details n (%)	Univariate Analysis OR	95 % CI	p	Multivariate Analysis 1 AOR	95 % CI	p
All		18396 (100%)	580 (100%)						
Sex	Male	9391 (51%)	100 (17%)	ref			ref		
	Female	9005 (49%)	480 (83%)	5.2	(4.2 - 6.5)	<0.001	5.5	(4.5 - 6.9)	<0.001
Age Group (years)	<50	10637 (58%)	113 (19.5%)	ref			ref		
	50+	7759 (42%)	467 (80.5%)	6.0	(4.8 - 7.3)	<0.001	4.9	(3.9 - 6.1)	<0.001
SIMD quintile	1/2 (most deprived)	6799 (37%)	122 (21%)	ref			ref		
	3/4/5 (least deprived)	11482 (62%)	447 (77%)	2.2	(1.8 - 2.7)	<0.001	2.0	(1.6 - 2.5)	<0.001
	Not Known	115 (1%)	11 (2%)	5.8	(3.0 - 11.1)	<0.001	7.6	(3.7 - 15.7)	<0.001

Figure legends:

Figure 1. Trends in HCV testing per week for (a) all tests, (b) those with clinical information but no mention of transfusion and (c) those with clinical information including transfusion.

Appendix 1: Scottish Government Campaign Poster "Think you've had a blood transfusion in the past?"